Wyeth Research

Wyeth

December 17, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0350 -- FDA Draft Guidance for Industry on Handling and Retention of BA and BE Testing Samples (67 FR 64401; October 18, 2002).

Dear Sir/Madam:

Wyeth Research is submitting written comments on the draft guidance for industry entitled, "Handling and Retention of BA and BE Testing Samples" dated August 2002.

Wyeth is one of the world's largest research-based pharmaceutical and health care companies. It is a leader in the discovery, development, manufacturing, and marketing of prescription drugs and over-the-counter medication, with leading products in women's health care, cardiovascular, central nervous system, anti-inflammatory, infectious disease, hemophilia, and oncology categories, and is also a major manufacturer of preventative vaccines.

We are submitting the enclosed comments in duplicate. Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance for industry.

Sincerely,

Roy J. Baranello, Jr.
Assistant Vice President
Worldwide Regulatory Affairs

02D-0350 C 9

Lines 339-400 – Text: "It is uncommon for study sponsors and/or drug manufacturers to conduct BA/BE studies in their own facility."

Comment: On the contrary, for study sponsors and/or drug manufacturers who have clinical trials/studies/pharmacology units operating within their clinical R&D organizations, it is reasonable and appropriate to carry out BA/BE investigations at these facilities. To state otherwise is to imply an element of impropriety about the practice that is not warranted. Therefore, we recommend that this sentence be deleted.

Line 349, Lines 361-362 and Lines 367-368 -- Text: For in-house studies, " It is recommended that a firm engage a third party for retention of reserve samples;" and " It is recommended that an independent, third party be available to witness dosing and random selection of reserve samples;" and "It is advised that an independent, third party be used for retention of reserve samples."

Comment: The repeated use of the similar terms "recommended" and "advised" imply that an independent third party should be used. However, adequate sampling, retention, and security procedures, similar to those used in GMP processes would rule out the need for the use of an independent third party.

Line 363 -- Text: "Reserve samples should be retained in a secure room in the clinical study unit."

Comment: As a practical matter, such a room would clearly be under the control of study unit or other sponsor staff. How is this statement to be reconciled with the content of lines 349 and 367-368?

Therefore, it is recommended that the Line 349 be revised to read, "Third parties may be engaged for retention of reserve samples." Similarly, Lines 361-362 should be amended to read, "An independent, third party may be used to witness dosing and random selection of reserve samples." Furthermore, Lines 367-368 should be revised to read "An independent third party may be used for retention of reserve samples."

Lines 251-253, 293-295, and 333-335 provide that "reserve samples for studies conducted by CROs, universities, hospitals, physician's offices, and SROs may be transferred to an independent third party if the testing facility does not have an adequate storage facility."

Comment: A similar disclaimer should be provided for studies conducted in-house. In addition, in-house testing reserve samples may also be stored at another in-house site (with the proviso that adequate controls and procedures are in place).